Koby Surgical
Innovations in Foot Surgery

K060026 p 1/1

JAN 26 2006

16350 Park Ten Place, Suite 101
Houston, TX 77084
Phone: 281.398.5656
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510(k) Summary

Date Prepared:	December 29, 2005
Sponsor:	Koby Surgical 16350 Park Ten Place, Suite 101 Houston, TX 77084
Company Contact:	Perry Forrester Phone: (281) 398-5656 Fax: (281) 398-5660
Device Trade Name:	Koby Surgical™ Internal Fixation System
Classification Name:	Smooth & threaded metallic bone fixation fasteners (21 CFR 888.3040, Product Code HWC, Class II)
Common Name:	Bone Screw or Internal Fixation Device (non-spinal)
Substantial Equivalence:	Documentation is provided which demonstrates the Koby Surgical Internal Fixation System to be substantially equivalent to other legally marketed devices.
Device Description:	The *Koby Surgical Internal Fixation System* consists of a series of cannulated and non-cannulated bone screws which vary in diameters and lengths. These screws are constructed from implant-grade titanium and are used to aid in the fixation of bones in the upper and lower extremities.
Intended Usage:	The *Koby Surgical Internal Fixation System* implants are intended for fixation of fractures, non-unions, arthrodeses and osteotomies of the small bones in the hand and foot. The implants are intended for single use only. These implants are not intended for attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.
Material:	Titanium Alloy (Ti-6AL-4V ELI)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 26 2006

Mr. Perry Forrester
President
Koby Surgical
16350 Park Ten Place, Suite 101
Houston, Texas 77084

Re: K060026
Trade/Device Name: Koby Surgical Internal Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: December 29, 2005
Received: January 4, 2006

Dear Mr. Forrester:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

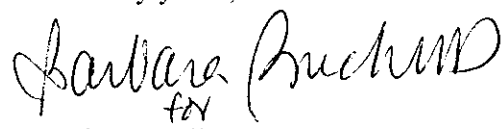
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson,
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-410 Division
D.O.
f/t:NKM:rrr: 1/25/06

Indications for Use

510(k) Number: Pending

Device Name: *Koby Surgical Internal Fixation System*

Indications For Use:

The *Koby Surgical Internal Fixation System* implants are intended for fixation of fractures, non-unions, arthrodeses and osteotomies of the small bones in the hand and foot. The implants are intended for single use only.

These implants are not intended for attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Ann MD for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060026